

R E M A R K S

The amendment to the specification merely introduces inherent properties of the deposited strain.

Favorable reconsideration and allowance of Applicants' claims are respectfully requested in view of the preceding amendment, the following comments and accompanying evidence.

A. The rejection of claim 1 "under 35 U.S.C. 112, second paragraph" is respectfully traversed. Claim 1 is directed to a biologically pure culture of a strain which is characterized in a manner which distinguishes it from all previously known strains. Having developed a new strain and having defined it by characterizing properties, Applicants' respectfully submit that they are entitled to claim that strain by its characterizing properties. The propriety of claiming a composition in terms of its properties is reflected, e.g., in the discussion under MPEP §2112. Note, particularly, the section under "EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY":

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. ..."

Property limitations can serve to distinguish claim subject matter from other products. *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988).

Applicants respectfully submit that there is nothing indefinite about the characterization set forth in claim 1, which includes the defining characteristics of the strain, which distinguishes it from all other known strains of *Saccharomyces cerevisiae*. Please note that Applicants are in the best position to know what they regard as their invention, and they confirm that claim 1 actually defines what they regard as their invention.

B. The rejection of claims 1 to 3 is also respectfully traversed. As previously pointed out, the strain characterized by claim 1 and further defined as yeast BPSC-15 deposited as NRRL 30630 under the Budapest Treaty Deposition Rules is clearly what they regard as their invention. A copy of papers (3 pages) confirming the filing under the Budapest Treaty Deposition Rules is submitted herewith.

C. The rejection of claim 1 "under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The characteristics set forth in claim 1 are inherent characteristics of the subject matter to which the entire application is directed. Being in possession of the strain having these inherent characteristics, Applicants unquestionably had possession of the invention called for by claim 1.

5. The rejection of claim 1 "under 35 U.S.C. 102(b) as anticipated by US 4560659, Asturias ... or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asturias" is also respectfully traversed. As pointed out in the previously cited *du Pont* Case:

To find anticipation of claims, the prior-art embodiments must possess the properties expressly recited in the claims.

It is clear from a reading of Asturias' examples that the yeast employed therein is significantly different from that claimed by Applicants. In Example 1 incubation was effected at 30°C. for 40 hours without agitation to obtain an ethanol concentration of 3.05g/100ml. In Applicants' Example 4 (page 22 of the specification) in a total of four hours 97g/L ethanol is produced. On page 23 of the specification (lines 23 and 24) the system run at 4 hour total RTD is 12 to 13% ethanol (v/v) with low residual sugars. These data from working examples illustrate a vast difference from anything extractable from Asturias.

In Asturias' Example 2, a flask was incubated at 30°C for 40 hours to produce 2.76g/100ml of ethanol. The difference is so great that it is ultimately clear to any artisan that the strain employed by Asturias is significantly different from that to which Applicants' claims are directed.

The reference indicates that a strain of *Saccharomyces cerevisiae* is able to ferment cane juice along with bits of the cane

fiber. Asturias suggests that the fermenter may be refilled with cut unextracted cane fiber and water for further fermentations. While not specifically addressed in this patent, it seems possible that yeast might be attaching to the cane fiber. There is no reference to the ability of the Asturias' yeast(s) to form flocs, to complete a fermentation in a short period of time, or to ferment to high ethanol concentrations under high osmotic pressure, which are key features of Applicants' yeast BPSC-15 deposited as NRRL 30630 under the Budapest Treaty Deposition Rules.

Asturias states (column 3, paragraph 2) "The particular yeast inoculum employed in the practice of the present invention is not narrowly critical. Illustrative yeast strains useful and preferred ... strains *Saccharomyces cerevisiae* L-180, L181, L-140 and L-169 (hybrid 5-non-flocculant)".

This contrasts with Applicants' yeast strain which is narrowly critical to the practice of the invention; strain BPSC-15/NRRL 306730 is the only strain, to Applicants' knowledge, able to form such stable floc pellets, release very few free yeast cells into the fermentation medium, and ferment sugars in such high osmolality solutions as described in the application.

The novel and useful properties which distinctly separate Applicants' yeast/process from other yeast/microbial processes (which similarly convert sugars to ethanol) are the properties of the presently claimed yeast to form strong stable floc pellets,

very low free cell densities (the broth remaining clear), and to have a high osmolality tolerance. These three properties, when exercised as taught in this patent application, lead to the ability to complete high speed, low effluent fermentations of molasses, cane juice, corn syrup, and other such sugar syrups in three different reactor configurations.

Further comparisons with Asturias' disclosure are noted in the following table.

Saccharomyces cerevisiae strain	Dale & Moelman BPSC-15 (NRRL-30630)	Asturias L-180, L-181, L-200 etc.
1. Forms stable floc ed pellets with very low free cell yeast density in the fermentation medium	YES- with very quick settling of pellets upon cessation of agitation	NO- one strain (L-169) is even characterized non-flocculant
2. Completes repeated batch fermentations in under 8 hours using floc yeast pellet with no need for cell centrifugation/recycle	YES- shows 36 repeated fermentations (Ex. 1) 104 g/L ethanol in 6 hours w/ Molasses substrate (Figure 4)	NO-only shows 2 consecutive fermentations 50.5 g/L ethanol in 24 hours in a second fermentation (Ex. 2)
3. Suggests addition of cane fiber	NO (Cane fiber would interfere with the settling of the yeast pellets)	YES
4. Produces high concentrations of ethanol in high salt (high osmolality) fermentations allowing reduced liquid effluent from the process	YES Show ability to ferment molasses to over 100 g/L ethanol with 30% recycle vinasse (Ex. 6, Fig. 5)	NO- only produces 50.5 g/L ethanol using cut cane substrate which has low associated salts/osmolality
5. Use of other 'generic' Saccharomyces strains also allows practice of invention	NO	YES
6. Allow high speed, low effluent fermentation of molasses, corn syrup, fruit sugars etc. using either Consec. Batch, Continuous Cascade, or Tower reactor configuration.	YES	NO

A recent journal article (copy herewith) in Sugar y Azucar, 1993, describes a current state of the art ethanol plant in Brazil which uses a 'modified Melle-Boinot process'. They are able to ferment a 20 brix 'mash' in fermenter cycles of 8 to 9 hours, similar to the rates Applicants achieve, as described in the subject application. However, the Brazilian process must centrifuge the yeast leaving the fermenter, treat the yeast concentrate 'cream' with sulfuric acid, and return a large volume of yeast 'cream' (17% of the fermenter volume) to the fermenters. All this ancillary yeast processing equipment is unnecessary using the presently claimed invention with Applicants' yeast strain. By forming stable floc pellets, which can be settled within the fermenter simply by stopping the agitation, results equivalent to the Brazilian Process are accomplished with no equipment, whereas state-of-the-art fermentations require expensive centrifuges, acid rinses, and yeast surge tanks.

A key property of Applicants' claimed yeast strain is the formation of stable large yeast floc pellets along with a low density of free yeast cells, as is clearly described in the application. This property, along with the high tolerance for ethanol/salts (high osmolality) is what allows high densities of yeast to be maintained in the fermenters, and gives the consequent high speed/low effluent fermentations of the invention.

With all due respect, the differences between that which is disclosed in the reference and that which is claimed are so enormous that no reasonable artisan could ever possibly conclude that the reference microorganism "inherently possesses the same characteristics as the claimed microorganism" the respective significant properties are extremely divergent.

Anticipation by inherency requires that 1) the missing descriptive matter be "necessarily present" in the prior art reference and that 2) it would be so recognized by persons of ordinary skill in the art. *Continental Can Co. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Oelrich and Divigard*, 212 U.S.P.Q. 323, 326 (CCPA 1981).

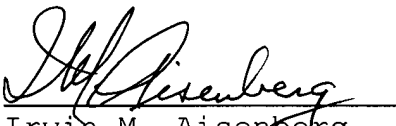
Reconsideration of the restriction requirement and the withdrawal of claims 4 to 17 from consideration are respectfully requested. Please note that each of claims 4 to 17 is at least ultimately dependent from and thus has all of the limitations of that which is called for by claims 1 to 3. Claims 4 to 17 are directed to a process of using the culture called for by claims 1 to 3 and are clearly part of one and the same invention. In a notice issued on February 28, 1996, the PTO announced that henceforth it would analyze process claims in accordance with the

Ochiai [37 U.S.P.Q.2d 1127 (Feb. Cir. 1995)] and *Brouwer* [37 U.S.P.Q.2d 1663 (Fed. Cir. 1995)] decisions of the Federal Circuit and treat as material limitations any recitation in process claims of the use of nonobvious starting materials or the making of nonobvious products. The newly developed strain and the claimed use thereof are part and partial of one and the same invention and are properly claimed in one and the same application. The claimed strain facilitate a high production of ethanol significantly more economically than state-of-the-art procedures.

Having overcome all outstanding grounds of rejection, Applicants' claims are now in condition for allowance, and early action toward that end is respectfully solicited.

Respectfully submitted,

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Enclosures: Proof of Budapest Treaty filing
Ethanol Dehydration at Usina Da Pedra